

Data Evaluation Report on the adsorption-desorption of the fenamidone metabolite RPA 411639 in soil

PMRA Submission Number {.....}

EPA MRID Number 45385826

Data Requirement: PMRA Data Code:
EPA DP Barcode:
OECD Data Point:
EPA Guideline: 163-1

Test material:

Common name: RPA 411639 (metabolite of fenamidone)

Chemical name

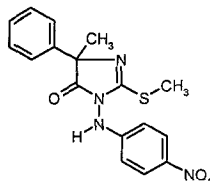
IUPAC: (S)-5-methyl-2-methylthio-3-(4-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one

CAS name: 4H-imidazol-4-one-3,5-dihydro-5-methyl-2-(methylthio)-3-[(4-nitrophenyl)amino]-5-phenyl-,(S)

CAS No: Not registered (p. 15)

Synonyms: S-enantiomer of the racemic compound RPA 406012

SMILES string:

Chemical Structure:

Primary Reviewer: Dana Worcester
Dynamac Corporation

QC Reviewer: Joan Harlin
Dynamac Corporation

Secondary Reviewer: Silvia Termes
EPA

Company Code: [for PMRA]
Active Code: [for PMRA]
Use Site Category: [for PMRA]
EPA PC Code:

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Date:

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Date:

Signed by Dynamac's reviewer on 2/14/2002

26 Aug, 2002



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Data Requirement: PMRA Data Code:
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EPA Guideline: 163-1

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Common name: RPA 411639 (metabolite of fenamidone)

Chemical name

IUPAC: (S)-5-methyl-2-methylthio-3-(4-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one

CAS name: 4H-imidazol-4-one-3,5-dihydro-5-methyl-2-(methylthio)-3-[(4-nitrophenyl)amino]-5-phenyl-, (S)

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Primary Reviewer: Dana Worcester
Dynamac Corporation

Signature: *Dana Worcester*
Date: 3/8/02

QC Reviewer: Joan Harlin
Dynamac Corporation

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Date: 3/8/02

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Date:

Company Code: [for PMRA]

Active Code: [for PMRA]

Use Site Category: [for PMRA]

EPA PC Code:

CITATION: Lowden, P. and N. Mahay. 1999. [¹⁴C]-RPA 411639 : Adsorption/desorption to and from four soils and a sediment. Unpublished study performed and sponsored by Rhône-Poulenc Agriculture Ltd., Essex, UK. Laboratory Project ID. 14709. RPA Document 202124. Study initiated February 10, 1999 and completed July 21, 1999.

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Administrative conclusions: This study is acceptable and provides mobility information on the metabolite RPA 411639. Together with the studies conducted with parent fenamidone and three other metabolites, it may be used to satisfy the 163-1 data requirements. The requirement for a mobility study using fenamidone as the test substance is satisfied by MRID 45385823.

EXECUTIVE SUMMARY:

The adsorption/desorption characteristics of the fenamidone metabolite [phenyl- $U-^{14}C$]RPA 411639 [(S)-5-methyl-2-methylthio-3-(4-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one] was studied in a silt loam soil [pH - 6.2, organic carbon - 0.5%] and sandy loam soil [pH - 4.8, organic carbon - 1.2%], each from the U.S. and a silt loam soil [pH - 8.1, organic carbon - 1.9%], clay sediment [pH - 7.4, organic carbon - 3.4%], and loam soil [pH - 7.0, organic carbon - 1.9%], each from the UK, in a batch equilibrium experiment. The experiment was conducted in accordance with the U.S. EPA Pesticide Guidelines Subdivision N, 163-1 and OECD Guidelines for Testing of Chemicals, "Adsorption/Desorption", Guideline 106 (May, 1981), and in compliance with the GLP standard 40 CFR Part 160 and OECD-GLP. The adsorption phase of the study was carried out by equilibrating air-dried soil and sediment with RPA 411639 at nominal concentrations of 13.5, 2.7, 0.55, and 0.1 mg a.i./kg at $20 \pm 1^\circ C$ for 40 hours in the dark. The equilibrating solution used was 0.01 M $CaCl_2$, with soil/solution ratios of 1:5 (w:v) for all four soils and one sediment. The desorption phase of the study was carried out by replacing the adsorption solution with an equivalent volume of sterilized, pesticide-free 0.01 M $CaCl_2$ solution and equilibrating in the dark for 24 hours at $20^\circ C$. The desorption phase was repeated four times.

The supernatant solution after adsorption and desorption was separated by centrifugation and triplicate aliquots were analysed for total radioactivity using LSC. Following desorption, one high-dose sample of each soil and sediment was extracted with acetonitrile and aliquots were analyzed by LSC. Radioactivity in the soil residue after the desorption or extraction step was determined by combustion. Aliquots (0.1-0.3 g) of air dried soil were combusted and analyzed by LSC.

HPLC analysis of supernatants from the soil residues indicated that RPA 411639 was relatively stable in the test solutions during the adsorption/desorption phase of the experiment. Supernatants analyzed by HPLC were from the highest treatment concentration. The mass balance was not reported at the end of adsorption phase of the study. The complete mass balance (adsorption and five desorption steps) was 100.7%, 97.5%, 98.7%, 96.2% and 96.7% of the

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applied in silt loam soil, silt loam soil, clay sediment, loam soil, and sandy loam soil, respectively.

After 40 hours of equilibration, 38.68-45.64%, 56.49-74.55%, 78.26-80.30%, 76.76-86.43%, and 64.89-74.20% of the applied RPA 411639 was adsorbed to the Bosket silt loam soil, Panholes silt loam soil, clay sediment, loam soil, and sandy loam soil, respectively (reviewer-calculated). Freundlich K_{ads} values were 3.17, 6.60, 18.48, 14.89, and 8.96 for the Bosket silt loam soil, Panholes silt loam soil, clay sediment, loam soil, and sandy loam soil, respectively; corresponding adsorption K_{oc} values ranged from 347 to 784. At the end of the desorption phase, 81.0-90.1%, 54.2-75.5%, 52.9-58.7%, 40.2-58.1%, and 69.3-75.1% of the adsorbed amount was desorbed from the Bosket silt loam soil, Panholes silt loam soil, clay sediment, loam soil, and sandy loam soil, respectively (reviewer-calculated). Following the final desorption step, Freundlich K_{des} values were 104.82, 22.01, 30.26, 27.80, and 28.07 for the Bosket silt loam soil, Panholes silt loam soil, clay sediment, loam soil, and sandy loam soil, respectively; corresponding K_{oc} values ranged from 890 to 20964. The Freundlich K_{des} and K_{oc} values were higher than those obtained for adsorption.

Results Synopsis: Adsorption and desorption values were determined using Freundlich isotherm equations. Amounts adsorbed and desorbed were calculated by the reviewer.

Soil type: Bosket silt loam

Amount adsorbed: 38.68-45.64% of the applied

Adsorption K_d : 3.17

Adsorption K_{oc} : 634

Amount desorbed: 81.0-90.1% of the adsorbed

Desorption K_d : 104.82

Desorption K_{oc} : 20964

Soil type: Panholes silt loam

Amount adsorbed: 56.49-74.55% of the applied

Adsorption K_d : 6.60

Adsorption K_{oc} : 347

Amount desorbed: 54.2-75.5% of the adsorbed

Desorption K_d : 22.01

Desorption K_{oc} : 1158

Soil type: Clay sediment

Amount adsorbed: 78.26-80.30% of the applied

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Adsorption K_d : 18.48
Adsorption K_{oc} : 543
Amount desorbed: 52.9-58.5% of the adsorbed
Desorption K_d : 30.26
Desorption K_{oc} : 890

Soil type: Loam
Amount adsorbed: 76.76-86.43% of the applied
Adsorption K_d : 14.89
Adsorption K_{oc} : 784
Amount desorbed: 40.2-58.1% of the adsorbed
Desorption K_d : 27.80
Desorption K_{oc} : 1463

Soil type: Sandy loam
Amount adsorbed: 64.89-74.20% of the applied
Adsorption K_d : 8.96
Adsorption K_{oc} : 746
Amount desorbed: 69.3-75.1% of the adsorbed
Desorption K_d : 28.07
Desorption K_{oc} : 2340

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study was conducted according to U.S. EPA Pesticide Assessment Guidelines Subdivision N, Series §163-1 (October 1982) and the EU Commission Directive 95/36/EC (July 1995). No deviations affected the validity of the study. Deviations from Subdivision N guidelines are:

The study was conducted using a metabolite rather than the parent compound.

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COMPLIANCE: This study was conducted in compliance with 40 CFR Part 160, EPA GLP and OECD-GLP. Signed and dated GLP, Quality Assurance, Data Confidentiality, and Study Certification statements were provided.

A. MATERIALS:

1. Test Material RPA 411639 (metabolite of fenamidone)

Chemical Structure:

Description: Not reported

Purity: Analytical purity: 100 (p. 16) Lot/Batch No. Not provided
Radiochemical purity: 97%
Batch No.: PCH1515
Specific activity: 1330 Mbq mmol
Locations of the label: Uniformly labeled in the phenyl ring

Storage conditions of test chemicals: Not provided

Physico-chemical properties of RPA 411639:

Parameter	Values	Comments
Water solubility	5.4 mg/L	
Vapour pressure	Not provided	
UV absorption	Not provided	
pK _a	Not provided	
K _{ow}	Not provided	
Stability of Compound at room temperature	Not provided	

Data were obtained from p. 18 of the study report.

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2. Soil Characteristics

Table 1: Description of soil collection and storage.

Description	Silt loam	Silt loam	Clay sediment	Loam	Sandy loam
Geographic location	Leland, MS	Kent, UK	Essex, UK	Essex, UK	Iola, Wisconsin
Pesticide use history at the collection site	Not provided	Not provided	Not provided	Not provided	Not provided
Collection procedures	Not provided	Not provided	Not provided	Not provided	Not provided
Sampling depth (cm)	Not provided	Not provided	Not provided	Not provided	Not provided
Storage conditions	Not provided	Not provided	Not provided	Not provided	Not provided
Storage length	Not provided	Not provided	Not provided	Not provided	Not provided
Soil preparation	Sieved, 2 mm	Sieved, 2 mm	Sieved, 2 mm	Sieved, 2 mm	Sieved, 2 mm

Data were obtained from p. 16 and Table 2, p. 30 of the study report.

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Table 2: Properties of the soils.

Property	Bosket 96/19	Panholes 97/10	Sediment 97/17	Faulkbourne 98/09	Rosholt 98/32
Soil Texture	Silt loam	Silt loam	Clay	Loam	Sandy loam
% sand	35.8	20.9	20.03	33.38	66.99
% silt	55.97	54.79	36.49	41.5	26.66
% clay	8.23	24.31	43.49	25.12	6.35
pH	6.2	8.1	7.4	7	4.8
Organic carbon (%)	0.5	1.9	3.4	1.9	1.2
CEC (meq/100 g)	5.7	65.7	62.3	10	17
Moisture at 1/3 atm (%)	25.41	25.86	31.25	20.7	12.8
Bulk density (lb/cu ft ³)	Not provided	Not provided	Not provided	Not provided	Not provided
Biomass (mg microbial C/100 g)	Not provided	Not provided	Not provided	Not provided	Not provided
Soil taxonomic classification	Fine-loamy, mixed, thermic mollic hapludalfs	Fine-silty, mixed, mesic typic eutrochrept	Not provided	Fine-loamy, mixed, mesic typic hapludalfs	Coarse-loamy, mixed typic glossoboralfs
Soil mapping unit (for EPA)	Not provided	Not provided	Not provided	Not provided	Not provided

Data were obtained from Table 2, p. 30 and Appendix VI, pp. 97-98 of the study report.

B. STUDY DESIGN:

1. Preliminary study: To determine whether the test substance adsorbed to borosilicate glass tubes, 75 mL of a solution containing 2.7 or 0.02 mg/L of [¹⁴C]RPA 411639 in 0.01M CaCl₂ were added to two sets of two borosilicate screw-capped glass tubes, and the tubes were tightly capped and shaken on an end-over-end shaker in the dark at 20 ± 1°C for 24 hours (p. 19). Aliquots of the solutions were analyzed for total radioactivity using LSC. Results showed that

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RPA 411639 did not adsorb to the glass tubes; the mean recovery was 98.2% (97.9-98.71%; p. 22; Table 3, p.31).

To determine the soil:solution ratio to be used in the definitive study, soil:solution ratios of 1:20, 1:10 and 1:5 were prepared by adding aliquots of a solution containing 1 mg/L of [14 C]RPA 411639 in 0.01M CaCl₂ to borosilicate screw-capped glass tubes containing 3, 6, and 15 g (dry weight equivalent) of each test soil and sediment (p. 19). The tubes were tightly capped, shaken by hand to suspend the soil, then shaken on an end-over-end shaker in the dark at $20 \pm 1^\circ\text{C}$ for 24 hours. The tubes were removed and centrifuged for 10 minutes at 2,000 rpm. Aliquots of the supernatants were analyzed for total radioactivity using LSC. Soil:solution ratios of 1:5 yielded recoveries of 18.7-54.2% of the applied in the supernatants (Table 4, p. 31). Data for soil:solution ratios 1:20 and 1:10 were not presented in Table 4 (see DER Comment 8).

To determine the equilibration time to be used in the definitive adsorption phase of the study, 75 mL of a 0.01 M CaCl₂ solution containing 1 mg/L of [14 C]RPA 411639 were added to borosilicate screw-capped glass tubes containing 15 g (dry weight equivalent) of each test soil and sediment (p. 19; Figure 1, p. 38). The tubes were shaken by hand to suspend the soil, then shaken on an end-over-end shaker in the dark at $20 \pm 1^\circ\text{C}$ for 1, 2, 4, 6, 24, 48, and 72 hours. The samples were centrifuged at 2,000 rpm for 10 minutes and triplicate aliquots of the supernatants were analyzed for total radioactivity using LSC. Results showed an initial, rapid decrease in radioactivity in the supernatants, that was followed by a gradual decrease, then little change after 24 hours (p. 23; Figure 3, p. 40).

To determine the equilibration time to be used in the definitive desorption phase of the study, 75 mL of a 0.01 M CaCl₂ solution containing [14 C]RPA 411639 were added to borosilicate screw-capped glass tubes containing 15 g (dry weight equivalent) of each test soil and sediment (p. 19; Figure 2, p. 39). The tubes were shaken on an end-over-end shaker in the dark at 20°C for 24 hours. The samples were centrifuged and the supernatants were decanted and replaced with pesticide-free 0.01M CaCl₂. The tubes were then placed in the dark at 20°C and shaken on an end-over-end shaker for 1, 2, 4, 6, 24, 48, and 72 hours (Figure 2, p. 39). The samples were centrifuged at 2,000 rpm for 10 minutes and triplicate aliquots of the supernatants were analyzed for total radioactivity using LSC. In the four test soils and one sediment, little change in the amount of radioactivity in solution was observed between 24 and 72 hours (p. 23; Figure 4, p. 41).

To determine the solubility of RPA 411639, approximately 1.3 mg of RPA 411639 was weighed into a 50-mL volumetric flask and 50 mL of deionized water was added to the flask (Appendix III, p. 73). The solution was mixed in an ultrasonic bath for approximately 24 hours at 20°C ,

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then filtered (0.45 μm); aliquots were analyzed using LSC. The solution was re-filtered (0.1 μm) and the radioactivity was determined using LSC. The solubility of RPA 411639 was determined to be 5.37 mg/L.

Based on the results of the preliminary studies, it was determined that the definitive study would be conducted using a soil:solution ratio of 1:5, an adsorption phase equilibration period of 40 hours, a desorption phase equilibration period of 24 hour, and a maximum solution concentration of 2.7 mg/L for each of the test soils and sediment (p. 23; Appendix III, p. 73).

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2. Definitive study experimental conditions:

Table 3: Study design for the adsorption phase.

Parameters		Bosket silt loam	Panholes silt loam	Clay sediment	Loam	Sandy Loam
Condition of soil (air dried/fresh)		Air-dried	Air-dried	Air-dried	Air-dried	Air-dried
Have these soils been used for other laboratory studies ? (specify which)		Yes, MRIDs 45385823, 45385824, 45385825, 45385828	Yes, MRIDs 45385823, 45385824, 45385825	Yes, MRID 45385825	Yes, MRID 45385823, 45385824, 45385825, 45385828	Yes, MRIDs 45385823, 45385824, 45385825
Soil (g/replicate)		15 g	15 g	15 g	15 g	15 g
Equilibrium solution used (name and concentration; eg: 0.01N CaCl ₂)		0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂
Control used (with salt solution only) (Yes/No)		No	No	No	No	No
Test material concentrations ¹	Nominal application rates (mg/kg)	13.5, 2.7, 0.55, 0.1	13.5, 2.7, 0.55, 0.1	13.5, 2.7, 0.55, 0.1	13.5, 2.7, 0.55, 0.1	13.5, 2.7, 0.55, 0.1
	Analytically measured concentrations (mg/kg)	11.1, 2.2, 0.34, 0.1	11.1, 2.2, 0.34, 0.1	11.1, 2.2, 0.34, 0.1	11.1, 2.2, 0.34, 0.1	11.1, 2.2, 0.34, 0.1
Identity and concentration of co-solvent, if any		Acetonitrile, 2 mg/mL	Acetonitrile, 2 mg/mL	Acetonitrile, 2 mg/mL	Acetonitrile, 2 mg/mL	Acetonitrile, 2 mg/mL
Soil:solution ratio		1:5	1:5	1:5	1:5	1:5

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Parameters		Basket silt loam	Panholes silt loam	Clay sediment	Loam	Sandy Loam
Initial pH of the equilibration solution, if provided		Not provided	Not provided	Not provided	Not provided	Not provided
No. of replica- tions	Controls	0	0	0	0	0
	Treatments	2	2	2	2	2
Equilibration	Time (hours)	40	40	40	40	40
	Temperature (°C)	20 ± 1	20 ± 1	20 ± 1	20 ± 1	20 ± 1
	Darkness (Yes/No)	Yes	Yes	Yes	Yes	Yes
	Shaking method	End-over-end shaker	End-over-end shaker	End-over-end shaker	End-over-end shaker	End-over-end shaker
	Shaking time (hours)	40	40	40	40	40
Method of separation of supernatant (eg., centrifugation)		Centrifugation	Centrifugation	Centrifugation	Centrifugation	Centrifugation
Centrifugation	Speed (rpm)	2,000	2,000	2,000	2,000	2,000
	Duration (min)	ca. 10	ca. 10	ca. 10	ca. 10	ca. 10
	Method of separation of soil and solution	Decantation	Decantation	Decantation	Decantation	Decantation

Data obtained from pp. 18, 20, Table 5, p. 31 of the study report.

1 Reviewer-calculated by multiplying the concentration (nominal/measured) by the volume of CaCl₂ solution used and dividing that number by the amount of soil used in the system (2.7 mg/L x 75 mL = 300 mg/15 g soil = 15 mg/kg).

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Table 4: Study design for the desorption phase.

Parameters		Bosket silt loam	Panholes silt loam	Clay sediment	Loam	Sandy loam
Were the soil residues from the adsorption phase used? If not, describe the method for adsorption using a separate adsorption Table		Yes	Yes	Yes	Yes	Yes
Amount of test material present in the adsorbed state/adsorbed amount (mg a.i./kg soil) ¹	13.5	4.1624	6.174	8.4739	8.2335	7.0046
	2.7	0.8837	1.3773	1.7185	1.7347	1.4571
	0.55	0.2033	0.3168	0.3672	0.3868	0.3347
	0.1	0.0428	0.07	0.075	0.0817	0.0692
No. of desorption cycles		5	5	5	5	5
Equilibration solution and quantity used per treatment for desorption (eg., 0.01M CaCl ₂)		0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂	0.01M CaCl ₂
Soil:solution ratio		1:5	1:5	1:5	1:5	1:5
Replications	Controls	0	0	0	0	0
	Treatments	2	2	2	2	2
Desorption equilibration	Time (hours)	24	24	24	24	24

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Parameters		Bosket silt loam	Panholes silt loam	Clay sediment	Loam	Sandy loam
	Temperature (°C)	20 ± 1	20 ± 1	20 ± 1	20 ± 1	20 ± 1
	Darkness	Yes	Yes	Yes	Yes	Yes
	Shaking method	End-over-end shaker	End-over-end shaker	End-over-end shaker	End-over-end shaker	End-over-end shaker
	Shaking time (hours)	24	24	24	24	24
Centrifugation	Speed (rpm)	2,000	2,000	2,000	2,000	2,000
	Duration (min)	10	10	10	10	10
	Method of separation of soil and solution	Not reported	Not reported	Not reported	Not reported	Not reported
Second - fifth desorption	Indicate if the method is same as the first desorption cycle.	Same	Same	Same	Same	Same

Data were obtained from p. 20 of the study report. Means were reviewer-calculated using Excel with data obtained from Appendix V, pp. 89-93 of the study report.

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3. Description of analytical procedures:

Extraction/clean up/concentration methods: Following the final desorption step, 75 mL of acetonitrile were added to one tube from each test soil and sediment treated at the highest concentration, and the tube was shaken to resuspend the soil (p. 20). The tubes were shaken on a wrist action shaker for 20 minutes, centrifuged for 10 minutes, and the supernatants were removed (method unspecified).

Total ^{14}C measurement: Aliquots of the supernatants were analyzed for total radioactivity using LSC (p. 20). Following the final desorption or extraction, the soil residues were air-dried, ground to a fine powder, and triplicate subsamples (0.1-0.3 g) were analyzed for total radioactivity by LSC following combustion (p. 21).

Non-extractable residues, if any: Not applicable.

Derivatization method, if used: A derivatization method was not employed in the study.

Identification and quantification of parent compound: Supernatants analyzed by HPLC were from the highest treatment concentration. Identification and quantification of the parent compound were performed by HPLC using the following operating conditions: Kromasil, KR 100 5C1 column (4.6 x 250 mm), gradient mobile phase of (A) acetonitrile:water (40:60, v:v) and (B) acetonitrile [percent A:B at 0 min. 100:0 (%), 10 min. 100:0 (%), 15 min. 0:100 (%), 20 min. 0:100 (%), 23 min. 100:0 (%), 32 min. 100:0 (%)], flow rate 1 mL/minute, with radiometric and UV (230 nm) detection (p. 21). The identity of the parent compound was confirmed by chromatographic comparison of the HPLC retention times of an unlabelled reference standard.

Identification and quantification of transformation products, if appropriate: Identification and quantification of transformation products were not performed..

Detection limits (LOD, LOQ) for the parent compound: The limits of detection for LSC and HPLC analyses of RPA 411639 were reported to be 0.018 ng/g and 0.005 $\mu\text{g/g}$, respectively (Appendix IV, p. 80). The limits of quantification for LSC and HPLC analyses were not reported.

Detection limits (LOD, LOQ) for the transformation products, if appropriate: Identification and quantification of transformation products were not performed.

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II. RESULTS AND DISCUSSION

A. TEST CONDITIONS: The stability of the test substance in solution during the definitive study for the four test soils and one sediment was confirmed, based on the results of HPLC analysis (Table 10, pp. 36-37). Degradation comprised $\leq 2.23\%$ of the applied radioactivity in all analyzed supernatants.

B. MASS BALANCE: The mass balance was not reported at the end of adsorption phase of the study. Mass balances were calculated by summing the total amount of RPA 411639 recovered in the adsorption and desorption solutions, the soil extracts, and unextracted soil residues. Mass balances were 100.7, 97.5, 98.7, 96.2, and 96.7% of the applied for the Bosket silt loam soil, Panholes silt loam soil, clay sediment, loam soil, and sandy loam soil, respectively (Table 6, pp. 32-33).

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Table 5: Recovery of RPA 411639, expressed as percentage of applied radioactivity, in soil after adsorption/desorption (n = 8; mean \pm s.d.).¹

Matrices	Bosket silt loam	Panholes silt loam	Clay sediment	Loam	Sandy loam
At the end of the adsorption phase					
Supernatant solution	52.53 ± 3.1	29.98 ± 6.5	16.95 ± 1.1	15.76 ± 3.5	27.73 ± 3.7
Solid phase (total ¹⁴ C)	Not determined				
Total recovery	Not determined				
At the end of the desorption phase					
Supernatant solution ²	41.44 ± 3.8	43.97 ± 2.6	44.49 ± 5.0	39.55 ± 4.4	49.98 ± 2.4
Solid phase (extracted) ³	--	--	--	--	--
Non-extractable residues in soil, if measured ³	7.0 ± 2.8	25.6 ± 7.8	37.7 ± 6.0	41.9 ± 8.1	19.29 ± 3.2
Total recovery	100.7 ± 4.3	97.5 ± 3.1	98.7 ± 5.6	96.2 ± 2.3	96.7 ± 2.8

¹ Means and standard deviations were reviewer-calculated using Excel and data obtained from Table 6, pp. 32-33 of the study report.

² Values represent cumulative radioactivity in desorption supernatants for all five desorption steps.

³ Single samples were extracted; the extracted and unextractable values for these samples are not included in the table. The respective extracted and unextractable values are 3.3% and 0.6% for the silt loam; 10.2% and 4.4% for the silt loam; 27.9% and 6.4% for the sediment; 27.3% and 6.4% for the loam; and 13.9% and 3.0% for the loam soil.

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Table 6: Concentration of RPA 411639 in the solid and liquid phases at the end of adsorption equilibration period (n = 2; mean \pm s.d.).¹

Concentration (mg a.i./kg)	Bosket silt loam			Panholes silt loam			Clay sediment		
	on soil (mg a.i./kg) ²	in solution (μ g a.i./mL)	% adsorbed ³	on soil (mg a.i./kg) ²	in solution (μ g a.i./mL)	% adsorbed ³	on soil (mg a.i./kg) ²	in solution (μ g a.i./mL)	% adsorbed ³
13.5	4.1624 \pm 0.1	1.346 \pm 0.0	38.68 \pm 0.5	6.1740 \pm 0.0	0.9265 \pm 0.0	56.49 \pm 0.4	8.4739 \pm 0.1	0.4695 \pm 0.0	78.26 \pm 0.1
2.7	0.8837 \pm 0.0	0.2585 \pm 0.0	40.97 \pm 1.8	1.3773 \pm 0.0	0.157 \pm 0.0	63.14 \pm 1.1	1.7185 \pm 0.0	0.0855 \pm 0.0	80.30 \pm 0.1
0.55	0.2033 \pm 0.0	0.052 \pm 0.0	44.32 \pm 3.1	0.3168 \pm 0.0	0.028 \pm 0.0	69.44 \pm 1.0	0.3672 \pm 0.0	0.0018 \pm 0.0	80.13 \pm 0.0
0.1	0.0428 \pm 0.0	0.0105 \pm 0.0	45.64 \pm 3.1	0.0700 \pm 0.0	0.005 \pm 0.0	74.55 \pm 0.6	0.0750 \pm 0.0	0.004 \pm 0.0	79.92 \pm 2.5

Concentration (mg a.i./kg)	Loam			Sandy loam		
	on soil (mg a.i./kg) ²	in solution (μ g a.i./mL)	% adsorbed ³	on soil (mg a.i./kg) ²	in solution (μ g a.i./mL)	% adsorbed ³
13.5	8.2335 \pm 0.0	0.505 \pm 0.0	76.76 \pm 0.3	7.0046 \pm 0.0	0.7625 \pm 0.0	64.89 \pm 0.3
2.7	1.7347 \pm 0.0	0.085 \pm 0.0	80.28 \pm 0.2	1.4571 \pm 0.0	0.141 \pm 0.0	67.66 \pm 1.9
0.55	0.3868 \pm 0.0	0.015 \pm 0.0	84.23 \pm 0.0	0.3347 \pm 0.0	0.025 \pm 0.0	72.64 \pm 0.0
0.1	0.0817 \pm 0.0	0.003 \pm 0.0	86.43 \pm 0.2	0.0692 \pm 0.0	0.005 \pm 0.0	74.20 \pm 1.0

¹ Means and standard deviations were reviewer-calculated using Excel and data obtained from Appendix V, pp. 83-93 of the study report.

² Reviewer-calculated by dividing soil concentration by treatment rate (4.22 μ g/g \times 15 g soil \div 162.253 μ g = 39.01%)

³ The amount adsorbed was calculated as the difference between the amount applied and the amount in the aqueous phase.

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Table 7: Concentration of RPA 411639 in the solid and liquid phases at the end of desorption (n = 2; total of all desorption phases).^{1,2}

Concentration (mg a.i./kg)	Bosket silt loam			Panholes silt loam			Clay sediment		
	on soil (mg a.i./kg)	in solution (µg a.i./mL)	% desorbed as % of the adsorbed ³	on soil (mg/kg)	in solution (µg a.i./mL)	% desorbed as % of the adsorbed ³	on soil (mg/kg)	in solution (µg a.i./mL)	% desorbed as % of the adsorbed ³
13.5	0.7705	0.810	90.1	1.896	0.908	75.5	3.745	1.032	58.5
2.7	0.118	0.179	88.7	0.4780	0.2015	68.9	0.786	0.202	58.7
0.55	0.0285	0.040	86.9	0.1335	0.0405	60.4	0.169	0.037	57.7
0.1	0.004	0.006	81.0	0.0345	0.008	54.2	0.033	0.010	52.9

Concentration (mg a.i./kg)	Loam			Sandy loam		
	on soil (mg/kg)	in solution (µg a.i./mL)	% desorbed as % of the adsorbed ³	on soil (mg/kg)	in solution (µg a.i./mL)	% desorbed as % of the adsorbed ³
13.5	3.713	0.975	58.1	2.133	1.052	75.1
2.7	0.868	0.185	53.9	0.431	0.222	73.6
0.55	0.2185	0.036	45.7	0.111	0.048	72.5
0.1	0.0505	0.007	40.2	0.023	0.01	69.3

¹ Means were reviewer-calculated using Excel and data obtained from Appendix V, pp. 83-87 of the study report.

² Each value in the solid phase is the amount present after the final desorption step and each value in the solution phase is the total amount desorbed; Total amount in solution during the 5 desorption steps were reviewer-calculated by summing amount in solution at each desorption, e.g.

0.45+0.199+0.089+0.045+0.026=0.809.

³ The % desorbed as % of the adsorbed was calculated for each sample by the reviewer as follows; [% desorbed (desorption 1 + desorption 2 + desorption 3 + desorption 4 + desorption 5)] ÷ (% total recovery - % adsorbed); e.g., 96.2 - 55.7 = 40.5; 20.4 + 8.9 + 4.1 + 2.1 + 1.1 = 36.6; (36.6 ÷ 40.5) x 100 = 90.3%.

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Table 8: Freundlich adsorption and desorption constants of RPA 411639 in the soils.¹

Soil	Adsorption				Desorption ²			
	K	1/N	R ²	K _{oc}	K _d	1/N	R ²	K _{oc}
Bosket silt loam	3.17	0.939	1.000	634	104.82	1.349	0.993	20964
Panholes silt loam	6.6	0.846	1.000	347	22.01	0.884	0.999	1158
Clay sediment	18.48	0.983	1.000	543	30.26	0.99	0.997	890
Loam	14.89	0.868	1.000	784	27.8	0.896	1	1463
Sandy loam	8.96	0.91	1.000	746	28.07	1.036	0.999	2340

¹ Data were obtained from Tables 7-8, p. 34 of the study report.

² Desorption values reported for the fifth desorption step.

K - Freundlich adsorption and desorption coefficients; 1/N - Slope of Freundlich adsorption/desorption isotherms.

K_{oc} - Coefficient adsorption per organic carbon (K_d or K x 100/% organic carbon).

R² - Regression coefficient of Freundlich equation.

C. ADSORPTION: After 40 hours of equilibration, 38.68-45.64%, 56.49-74.55%, 78.26-80.30%, 76.76-86.43%, and 64.89-74.20% of the applied RPA 411639 was adsorbed from the Bosket silt loam soil, Panholes silt loam soil, clay sediment, loam soil, and sandy loam soil, respectively (reviewer-calculated). Freundlich K_{ads} values were 3.17, 6.60, 18.48, 14.89, and 8.96 for the Bosket silt loam soil, Panholes silt loam soil, clay sediment, loam soil, and sandy loam soil, respectively; corresponding K_{oc} values were 634, 347, 543, 784, and 746 (Table 7, p. 34).

D. DESORPTION: At the end of the desorption phase, 81.0-90.1%, 54.2-75.5%, 52.9-58.7%, 40.2-58.1%, and 69.3-75.1% of the adsorbed ¹⁴C was desorbed from the Bosket silt loam soil, Panholes silt loam soil, clay sediment, loam soil, and sandy loam soil, respectively (reviewer-calculated). Following the last desorption step, Freundlich K_{des} values were 104.82, 22.01, 30.26, 27.80, and 28.07 for the Bosket silt loam soil, Panholes silt loam soil, clay sediment, loam soil, and sandy loam soil, respectively; corresponding desorption K_{oc} values were 20964, 1158, 890, 1463, and 2340 (Table 8, p. 34).

III. STUDY DEFICIENCIES: The objective of this study was to study the sorptive behavior of the fenamidone metabolite RPA 411639 in four soils and one sediment with varying soil characteristics. None of the study deficiencies noted are considered to be of sufficient concern to cause the study to be judged scientifically invalid. However, since a metabolite of fenamidone

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was studied rather than the parent compound, this study cannot be used to fulfill Subdivision N Guideline §163-1. This study does provide useful supplemental information on the mobility of RPA 411639 in four soils and a sediment.

IV. REVIEWER'S COMMENTS:

1. The Panholes silt loam and loam soils and the clay sediment were foreign in origin. However, these soils and sediment were characterized according to the USDA soil textural classification system and were comparable to soils found in the United States.
2. The study author concluded that the minor amount of RPA 411639 degradation that occurred in the test soils and sediment during the definitive study would not significantly affect the adsorption and desorption coefficients.
3. The $1/n$ values associated with the Freundlich K values for a silt loam and loam soil were below 0.9; $1/n$ respective values associated with the Freundlich K_{ads} were 0.846 and 0.868 (Table 7, p. 34). If the $1/n$ value is not within the range of 0.9 to 1.1, then the Freundlich isotherm may not adequately or accurately represent the adsorption of the compound across all concentrations.
4. RPA 411639 has medium to low mobility, based on its K_{oc} values (p. 25). An approximately linear relationship between the concentration adsorbed and the concentration in solution was noted for the Bosket silt loam and clay sediment. Some slight concentration-related effects for the Panholes silt loam, loam, and sandy loam soils were noted by the study author. The author added that under field conditions, once RPA 411639 is adsorbed to the soil, it will be less readily desorbed, so that its potential to move into deeper soil layers is reduced. Similar behavior was noted for the mobility of fenamidone and other fenamidone transformation products (reviews included in this submission).
5. Sample storage intervals and conditions were not reported.. The maximum sample storage intervals were not reported. The definitive experiment was conducted from May 10-May 17, 1999 and HPLC of adsorbates, desorbates, and solvent extracts was conducted on May 13-June 3, 1999 (Table 1, p. 29). Therefore, it appears that the samples were stored prior to analysis
6. Control samples were not employed in the definitive study.

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7. The amount of RPA 411639 (μg) adsorbed to the soils and sediment was calculated as the difference between the amount applied and the amount in the supernatant solution.
8. Table 4 of the study report incorrectly reports the preliminary experiment soil:solution ratios were 1:10, 1:5, and 1:3 (p. 31). The correct soil:solution ratios used in the preliminary experiment were 1:20, 1:10 and 1:5, and are reported as such in the study review (p. 19).
9. Method detection limits were not reported. Both method detection limits and limits of quantitation should be reported to allow the reviewer to evaluate the adequacy of the method.

V. REFERENCES: The following references were cited in the study:

United States Environmental Protection Agency Pesticide Assessment Guidelines, Subdivision N, October 18, 1982.

EU Commission Directive 95/36/EC July 1995, amending Council Directive 91/414/EEC.

OECD Method 106, Paris 1981.

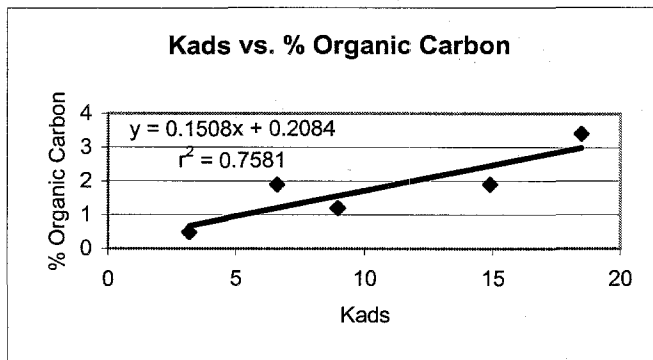
McCall, P.J., R.L. Swann, D.A. Laskowski, S.M. Unger, S.A. Vrona, and H.J. Dishburger. 1980. *Bull. Environ Contam. Toxicol.* 24, pp. 190-195.

Attachment 1
Excel Spreadsheets

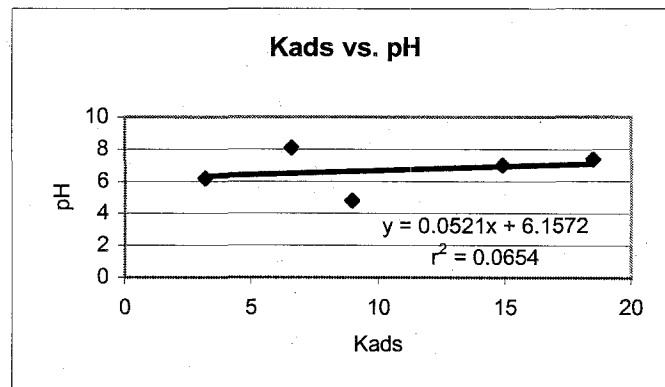
Chemical Name
MRID
Guideline No.

Fenamidone Metabolite RPA 411639
45385826
163-1

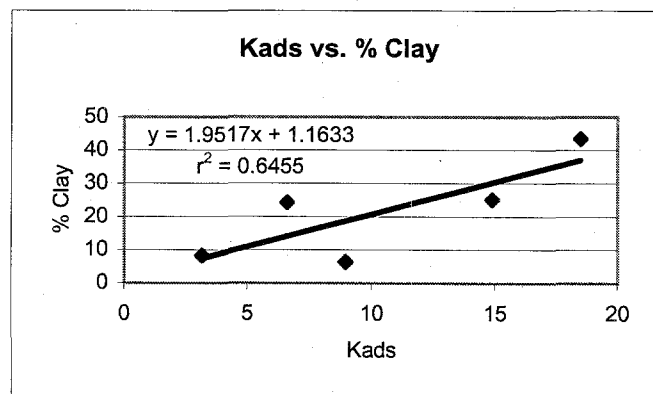
Soil	Kads	% Organic Carbon
Silt loam	3.17	0.5
Silt loam	6.6	1.9
Sediment	18.48	3.4
Loam	14.89	1.9
Sandy loam	8.96	1.2



Soil	Kads	pH
Silt loam	3.17	6.2
Silt loam	6.6	8.1
Sediment	18.48	7.4
Loam	14.89	7
Sandy loam	8.96	4.8



Soil	Kads	% Clay
Silt loam	3.17	8.23
Silt loam	6.6	24.31
Sediment	18.48	43.49
Loam	14.89	25.12
Sandy loam	8.96	6.35



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Table 4/6

Adsorbed		Silt loam	Silt loam	Sediment	Loam	Sandy loam
	2.7	4.22003	6.1999	8.5418	8.23742	7.00114
	2.7	4.10472	6.14802	8.40598	8.22951	7.00809
	average	4.162375	6.17396	8.47389	8.233465	7.004615
	s.d.	0.081536	0.0366847	0.096039	0.005593	0.00491439
	0.54	0.86632	1.36532	1.69119	1.73174	1.42215
	0.5	0.90108	1.38921	1.74581	1.7376	1.49211
	average	0.8837	1.377265	1.7185	1.73467	1.45713
	s.d.	0.024579	0.01689278	0.038622	0.004144	0.04946919
	0.11	0.19483	0.31392	0.36598	0.38503	0.33555
	0.11	0.2117	0.31961	0.36842	0.38851	0.33392
	average	0.203265	0.316765	0.3672	0.38677	0.334735
	s.d.	0.011929	0.00402344	0.001725	0.002461	0.00115258
	0.02	0.04074	0.06982	0.07276	0.08246	0.06868
	0.02	0.04487	0.07027	0.0773	0.08097	0.06968
	average	0.042805	0.070045	0.07503	0.081715	0.06918
	s.d.	0.00292	0.0003182	0.00321	0.001054	0.00070711

Table 5

Ads. Supernatant		Silt loam	Silt loam	Sediment	Loam	sandy loam
	2.7	55.7	38.1	18.1	20.4	31.9
	2.7	56.1	38.5	18.1	20.2	32.6
	0.54	55	33.1	16.4	17.2	30.9
	0.54	52.2	32	16.4	17.2	28.4
	0.11	52.7	27.5	16.4	13.6	25.1
	0.11	48.9	26.2	16.5	14.1	25.2
	0.02	51.9	22.7	18.5	11.6	24.5
	0.02	47.7	21.7	15.2	11.8	23.2
	average	52.525	29.975	16.95	15.7625	27.725
	s.d.	3.069085	6.48443191	1.147668	3.500995	3.70086862

Table 5

Des. Supernatant		Silt loam	Silt loam	Sediment	Loam	Sandy loam
	2.7	36.6	43.8	46	44.2	47.6
	2.7	35.9	44	46.2	44.5	47.8
	0.54	40.9	45.9	46.6	42.3	50.5
	0.54	40.6	44.3	44.7	41.4	49.3
	0.11	42.4	45.5	33.1	39.2	51.9
	0.11	43.2	41.5	45.5	36.7	49
	0.02	46.3	42.8	50.1	36.1	54.7
	0.02	45.6	37.9	43.7	32	49
	average	41.4375	43.9714286	44.4875	39.55	49.975
	s.d.	3.780755	2.5614937	4.964859	4.379498	2.36144629

Table 5
Combusted

	Silt loam	Silt loam	Sediment	Loam	Sandy loam
2.7	4.2	13.7	31.2	30.1	14.8
0.54	6	20.7	33.3	35.7	16.2
0.54	4.4	19.9	31.1	35.9	19.6
0.11	6.2	30.7	46.4	43.8	17.7
0.11	6.6	26.6	38.6	46.5	20.6
0.02	10.8	32.5	42.2	52.2	23.7
0.02	10.9	35.4	41.1	49.1	22.4
average	7.014286	25.6428571	37.7	41.9	19.2857143
s.d.	2.770336	7.83961248	5.964897	8.127935	3.24470264

Table 5
Recovery

	Silt loam	Silt loam	Sediment	Loam	Sandy loam
2.7	96.2	96.6	98.4	98.5	96.4
2.7	97.4	96.3	95.5	94.8	95.2
0.54	101.9	99.8	96.3	95.1	97.7
0.54	97.2	96.2	92.2	94.6	97.3
0.11	101.4	103.7	95.9	96.5	94.8
0.11	98.7	94.2	100.6	97.3	94.7
0.02	108.9	98.1	110.8	99.8	102.8
0.02	104.2	95	100	93	94.5
average	100.7375	97.4875	98.7125	96.2	96.675
s.d.	4.289501	3.0512	5.579154	2.252618	2.76082286

Table 6
Solution

	Silt loam	Silt loam	Sediment	Loam	Sandy loam
2.7	1.34	0.922	0.469	0.508	0.755
2.7	1.352	0.931	0.47	0.502	0.77
average	1.346	0.9265	0.4695	0.505	0.7625
s.d.	0.008485	0.00636396	0.000707	0.004243	0.0106066
0.54	0.265	0.16	0.086	0.085	0.147
0.54	0.252	0.154	0.085	0.085	0.135
average	0.2585	0.157	0.0855	0.085	0.141
s.d.	0.009192	0.00424264	0.000707	0	0.00848528
0.11	0.054	0.028	0.0018	0.015	0.025
0.11	0.05	0.027	0.0018	0.015	0.025
average	0.052	0.0275	0.0018	0.015	0.025
s.d.	0.002828	0.00070711	0	0	0
0.02	0.011	0.005	0.004	0.002	0.005
0.02	0.01	0.005	0.003	0.003	0.005
average	0.0105	0.005	0.0035	0.0025	0.005
s.d.	0.000707	0	0.000707	0.000707	0

Table 6
% adsorbed

	Silt loam	Silt loam	Sediment	Loam	Sandy loam
2.7	39.01315	56.8074228	78.35403	76.5677	65.0908663
2.7	38.35158	56.1762162	78.17111	76.94369	64.6956008
average	38.68236	56.4918195	78.26257	76.7557	64.8932335
s.d.	0.467796	0.44633051	0.129346	0.265867	0.27949489
0.54	39.68836	62.3686375	80.20046	80.16044	66.3535121
0.54	42.2555	63.9169249	80.39414	80.39845	68.9740192
average	40.97193	63.1427812	80.2973	80.27944	67.6637656
s.d.	1.815245	1.09480451	0.136953	0.168292	1.85297832
0.11	42.09845	68.7290238	80.1109	84.20822	72.6224784
0.11	46.55096	70.1549255	80.15101	84.25993	72.6508121
average	44.3247	69.4419746	80.13095	84.23408	72.6366452
s.d.	3.148406	1.00826474	0.028361	0.03656	0.02003494
0.02	43.40155	74.1002117	78.10271	86.25526	73.5085227
0.02	47.87234	75	81.74098	86.60014	74.89301
average	45.63695	74.5501059	79.92184	86.4277	74.2007664
s.d.	3.161324	0.6362464	2.572643	0.243869	0.97898033

Table 7
On soil

	Silt loam	Silt loam	Sediment	Loam	Sandy loam
2.7	0.826	1.932	3.784	3.719	2.173
2.7	0.715	1.859	3.705	3.707	2.093
average	0.7705	1.8955	3.7445	3.713	2.133
s.d.	0.078489	0.0516188	0.055861	0.008485	0.05656854
0.54	0.086	0.448	0.752	0.858	0.389
0.54	0.15	0.508	0.819	0.878	0.473
average	0.118	0.478	0.7855	0.868	0.431
s.d.	0.045255	0.04242641	0.047376	0.014142	0.05939697
0.11	0.022	0.122	0.169	0.213	0.104
0.11	0.035	0.145	0.169	0.224	0.117
average	0.0285	0.1335	0.169	0.2185	0.1105
s.d.	0.009192	0.01626346	0	0.007778	0.00919239
0.02	0.002	0.032	0.028	0.049	0.019
0.02	0.006	0.037	0.038	0.052	0.026
average	0.004	0.0345	0.033	0.0505	0.0225
s.d.	0.002828	0.00353553	0.007071	0.002121	0.00494975

Table 7

Total Solution

	Silt loam	Silt loam	Sediment	Loam	Sandy loam
2.7	0.809	0.832	1.036	0.968	1.042
2.7	0.811	0.984	1.028	0.982	1.061
average	0.81	0.908	1.032	0.975	1.0515
s.d.	0.001414	0.10748023	0.005657	0.009899	0.01343503
0.54	0.182	0.206	0.203	0.187	0.223
0.54	0.176	0.197	0.201	0.183	0.22
average	0.179	0.2015	0.202	0.185	0.2215
s.d.	0.004243	0.00636396	0.001414	0.002828	0.00212132
0.11	0.04	0.043	0.03	0.037	0.049
0.11	0.04	0.038	0.044	0.034	0.047
average	0.04	0.0405	0.037	0.0355	0.048
s.d.	0	0.00353553	0.009899	0.002121	0.00141421
0.02	0.006	0.008	0.01	0.007	0.011
0.02	0.006	0.008	0.009	0.006	0.009
average	0.006	0.008	0.0095	0.0065	0.01
s.d.	0	0	0.000707	0.000707	0.00141421

Table 7

Total Solution

	Silt loam	Silt loam	Sediment	Loam	Sandy loam
2.7	90.37	74.87	57.29	56.59	73.80
2.7	89.83	76.12	59.69	59.65	76.36
average	90.10	75.50	58.49	58.12	75.08
s.d.	0.38	0.89	1.70	2.16	1.81
0.54	87.21	68.82	58.32	54.30	75.60
0.54	90.22	69.00	58.97	53.42	71.55
average	88.71	68.91	58.65	53.86	73.58
s.d.	2.13	0.13	0.46	0.62	2.86
0.11	87.06	59.71		47.29	74.46
0.11	86.75	61.03	57.67	44.11	70.50
average	86.91	60.37	57.67	45.70	72.48
s.d.	0.22	0.93	#DIV/0!	2.25	2.80
0.02	81.23	56.76	54.28	40.93	69.86
0.02	80.71	51.71	51.53	39.41	68.72
average	80.97	54.23	52.91	40.17	69.29
s.d.	0.37	3.58	1.94	1.08	0.80

Attachment 2

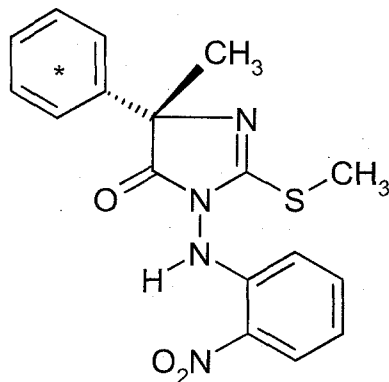
Structures of Parent and Transformation Products

RPA 413255

IUPAC name: (S)-5-Methyl-2-methylthio-3-(2-nitrophenylamino)-5-phenyl-3,5-dihydroimidazol-4-one

CAS name: 4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-3-(2-nitrophenylamino)-5-phenyl-, (S)-

CAS #: N/A



* Position of [¹⁴C] radiolabel